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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PETER J. SHANK and F. ANTHONY HEADLEY, JR.

Appeal 2008-5540
Application 10/720,176
Technology Center 3700

Decided: December 18, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composite stent. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 2, 3, 7, 22-24, and 28-35 stand finally rejected and are on appeal (Final Rejection 1).[1] Claims 23 and 29 are representative and read as follows:

> Claim 23. A composite stent comprising:
> a bioabsorbable stent; and
> a self-expanding metal stent releasably engageable within said bioabsorbable stent for insertion within a body lumen as a unit, said self-expanding metal stent biased to position said bioabsorbable stent into engagement with the body lumen.
>
> Claim 29. A method of treatment comprising the steps of:
> inserting a composite stent structure into a body lumen, said composite stent structure including an inner stent being made of a self-expanding metal, said inner stent being within an outer stent said outer stent being made of a bioabsorbable material;
> expanding said inner stent to cause said outer stent to be positioned into contact with an inner wall of the body lumen; and
> allowing for normal functioning of the body lumen by transporting a bodily substance through said composite stent structure.

Claims 2, 3, 7, 22-24, and 28-35, all of the appealed claims, stand rejected under 35 U.S.C. § 102(e) as anticipated by Hossainy[2] (Ans. 3).

ANTICIPATION

Issue

The Examiner's rejection reads as follows:

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[1] The Claims Appendix in the Appeal Brief inadvertently failed to include claim 22 (*see* Ans. 2).
[2] U.S. Patent No. 6,656,216 B1 (filed Dec. 2, 2003).

> Hossainy et al. discloses a composite stent comprised of an outer stent (209) and an inner stent (100) wherein the outer stent is comprised of a bioabsorbable material (col. 4, lines 1-30) and exerts a radial force in an outward direction (col. 3, lines 44-56) and the inner stent is comprised of a metallic material (col. 2, lines 50-65) and also provides a radially outward force (col. 2, lines 60-col. 3, line 10).

(Ans. 3.)

Appellants contend that the Examiner erred in finding that Hossainy meets the limitation in the claims requiring an outer stent, because structures 209 and 302, shown in Hossainy as being present on the outside of a stent, cannot themselves be considered stents when the claims are properly interpreted consistently with the Specification (App. Br. 10-15).

Given the positions advanced by the Examiner and Appellants, the issue with respect to this rejection is whether the Examiner erred in finding that Hossainy discloses structures that meet the limitations requiring the claimed composite stents to have an outer stent.

Findings of Fact ("FF")

1. Hossainy discloses a "composite stent" (Hossainy, abstract). Hossainy discloses that its stent has a "regioselective coating [which] may contain a therapeutic agent or a radio-opaque material" (*id.* at col. 1, ll. 8-9).

2. Figure 2 of Hossainy, reproduced below, "is an illustration of a stent implanted in a vessel according to one embodiment of the invention" (Hossainy, col. 2, ll. 35-36):

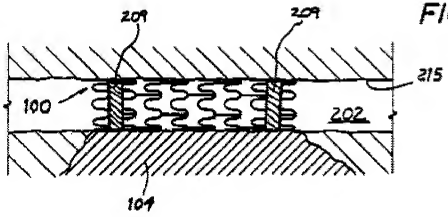

FIG. 2

Figure 2 of Hossainy shows stent 100 "implanted within a tubular vessel **202** at or near the site **204** [*sic,* **104**] of a stenosis to provide mechanical support to the lumen wall **215** of tubular vessel **202**" (Hossainy, col. 2, l. 66 through col. 3, l. 2).

3. Hossainy discloses that the stent shown in Figure 2 has "bands **209** made of a regioselective material that covers only selected discrete regions of the stent. In other embodiments, the regioselective material may be applied to stent **200** [*sic,* **100**] as strips, as a conformal coating, or as a compression-fitted sleeve" (Hossainy, col. 3, ll. 4-8).

4. Hossainy discloses that regioselective bands 209 "allow[] simultaneous delivery of radiation and drug dosimetries. Additionally, use of bands **209** permits the tailoring of radiation and/or drug dosimetries within a desired range at discrete areas of the stent, such as near the stent ends, where restenosis is prone to occur" (Hossainy, col. 3, ll. 10-14).

5. Hossainy discloses that the regioselective materials constituting bands 209 can be "blood compatible matrices and bioactive drugs [which] may be bio-absorbable" (Hossainy, col. 3, ll. 62-63; *see also* col. 4, ll. 1-49).

6. Hossainy discloses that, in one embodiment, "materials used to form regioselective bands **209** or strips (not shown) are viscoelastic materials having a high creep compliance because such materials are easily expandable and typically exert a gradual and weak restoring force that avoids collapsing or substantially deforming an expanded stent over time" (Hossainy, col. 3, ll. 44-49).

7. Hossainy discloses that "creep compliance is the ratio of strain to the applied stress" and that "materials having a high creep compliance, such as purely viscous materials, tend to exert a gradual and weak restoring force when compressed or stretched" (Hossainy, col. 3, ll. 33-43).

8. Hossainy discloses that, in one embodiment, the regioselective material of bands 209 can be applied to an expandable stent before expansion, but that "it is important to choose a regioselective material that will expand as stent **200** [*sic,* **100**] expands . . . without exerting a harmful compressive restoring force" (Hossainy, col. 3, ll. 23-26).

9. Regarding their disclosed stent, Appellants' Specification discloses that, "[t]he outer element may be, for example, a bioabsorbable stent typically constructed of a relatively non-resilient material such that the outer bioabsorbable stent may not be self-expanding and subject to migration within the lumen over time" (Spec. [0016]).

10. The Specification further discloses that, "[i]n contrast, the inner element may be, for example, and without limitation, a removable self-expanding metal stent (SEMS) used to urge and maintain the position of the outer element in the body lumen" (Spec. [0016]).

11. The Specification also discloses that "[t]he outer element may comprise (i) a mesh; (ii) a graft; (iii) a tube; (iv) a stent or (v) a similar structure" (Spec. [0021]).

12. The Specification discloses:

> An[] advantage of the present invention is that the outer element is not required to support the lumen walls by itself. The inner element may assist the outer element in this respect. Therefore, the outer element may have a lower profile, such as a smaller diameter filament or a flat filament. Through the interaction of the inner element and the outer element the final body lumen diameter, with the stent in place, will have a larger diameter.

(Spec. [0038].)

Principles of Law

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

It is well settled that, "[t]o anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

It is also well settled that during examination, the PTO must interpret terms in a claim using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the

applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

"A patent applicant is free to recite features of an apparatus either structurally or functionally." *Schreiber*, 128 F.3d at 1478. However, "'[f]unctional' terminology may render a claim quite broad . . .[;] a claim employing such language covers *any and all* embodiments which perform the recited function." *In re Swinehart*, 439 F.2d 210, 213 (CCPA 1971).

Moreover, as stated in *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (quoting *In re Swinehart*, 439 F.2d at 212-13):

> [W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

See also, In re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990) ("[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.").

Analysis

Appellants present separate arguments with respect to the apparatus and product claims. We select claim 23 as representative of the apparatus claims. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Claim 23 recites a composite stent that has two components, (a) a "bioabsorbable stent," and (b) a self-expanding metal stent releasably engageable within the bioabsorbable stent for insertion within a body lumen

as a unit, the self-expanding metal stent being biased to position the bioabsorbable stent into engagement with the body lumen.

Appellants do not argue, and therefore concede, that Hossainy meets the limitations in claim 23 directed to the inner metal stent. *See* 37 C.F.R. § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown.").

As to the limitation in claim 23 requiring the claimed composite stent to have an outer "bioabsorbable stent," Appellants argue that "[n]owhere in the specification is it disclosed or suggested that [the] claimed stents - whether inner, outer or composite - are any other type of structural devices than a body lumen or vessel support device that both can be compressed and expanded from a collapsed configuration" (App. Br. 11; *see also* Reply Br. 3).

Appellants' arguments do not appear to be consistent in scope with the Specification's disclosure. The Specification states that the outer element of the disclosed composite stent "may be, for example, a bioabsorbable stent typically constructed of a relatively non-resilient material such that the outer bioabsorbable stent may *not be* self-expanding and subject to migration within the lumen over time" (Spec. [0016] (FF 9) (emphasis added)).

Because it discloses that the outer stent can be made of a non-resilient material that is not self-expanding, it does not appear that the Specification consistently refers to a "stent" as being a lumen or vessel support that "both can be compressed and expanded from a collapsed configuration," as Appellants argue (App. Br. 11). Moreover, the Specification further states

that, because of the supportive function of the inner element, one "advantage of the present invention is that the outer element is not required to support the lumen walls by itself" (Spec. [0038] (FF 12)).

While the Specification does state that the "outer element" may be something other than a "stent" per se (*see* FF 11), paragraph [0038] suggests that the outer element, whether a stent or another structure, need not be able to support the walls of a lumen by itself. Thus, Appellants' argument that the claimed outer stent must be capable, by itself, of supporting the walls of lumen, is not necessarily consistent with the scope of the Specification's supporting disclosure.

Nonetheless, even assuming for argument's sake that the term "bioabsorbable stent" requires the structure to be a "body lumen or vessel support device that both can be compressed and expanded from a collapsed configuration" as argued by Appellants (App. Br. 11), a preponderance of the evidence supports the Examiner's finding that Hossainy meets that interpretation of claim 23.

Specifically, Hossainy discloses that its "composite stent" (Hossainy, abstract (FF 1)) has bands 209 made of "a regioselective material" on the outside of an expandable metal stent element (FF 2-3), and that the regioselective material can be bioabsorbable (FF 5). Hossainy also discloses that the material on the outer surface of its inner stent element can "a compression-fitted sleeve" (Hossainy, col. 3, l. 8) (FF 3)), made of "viscoelastic materials having a high creep compliance because such materials are easily expandable and typically exert a gradual and weak restoring force that avoids collapsing or substantially deforming an expanded stent over time" (Hossainy, col. 3, ll. 45-49 (FF 6)).

Thus, because Hossainy discloses that the material on the outer surface of its inner stent element can be a sleeve which is compression fitted onto the stent, but which also resists the compressive forces that cause the inner stent to collapse over time, we agree with the Examiner that it was reasonable to find that Hossainy's outer element would be capable of providing support to a vessel or other lumen. Moreover, because Hossainy discloses that the outer element can be applied before the stent is expanded (FF 8), Hossainy's outer structure meets the requirements that a stent be compressible and expandable.

Appellants argue that the outer structure of Hossainy's stent does not meet the functional requirements of being a stent because "[b]ands 209 are explicitly disclosed as being 'viscoelastic materials having a high creep compliance because such materials are easily expandable and typically exert a gradual and weak *restoring force* that avoids collapsing or substantially deforming an expanded stent over time'" (App. Br. 13 (quoting Hossainy, col. 3, ll. 44-49) (emphasis Appellants')).

Appellants urge that "[i]n context, the restoring force that bands 209 apply about stent 100 is without exception an inward directed force and does not include any radial force in an outward direction. Bands 209 are not disclosed or suggested as being any body lumen or vessel support device" (App. Br. 13). Thus, Appellants argue, "bands 209 in exerting restoring forces, i.e., collapsing forces, on stent 100 oppose application of radial outward forces with their inward directed forces" (*id.*).

We disagree with Appellants' interpretation of Hossainy. While Hossainy does disclose that the outer portion of its composite stent exerts "a gradual and weak restoring force," Hossainy states that the restoring force

"avoids collapsing or substantially deforming an expanded stent over time" (Hossainy, col. 3, ll. 44-49 (FF 6)).

Moreover, Hossainy discloses that the high creep compliance materials used to make the outer materials of its composite stents "tend to exert a gradual and weak restoring force *when compressed* or stretched" (Hossainy, col. 3, ll. 33-43 (FF 7) (emphasis added)). Thus, because its outer covering exerts a restorative force in response to compression, we agree with the Examiner that it was reasonable to conclude that Hossainy's outer covering would provide at least some support to a lumen, particularly given the additional disclosure that the restoring force "avoids collapsing or substantially deforming an expanded stent over time" (Hossainy, col. 3, ll. 44-49 (FF 6)).

Therefore, because Hossainy discloses that the outer covering of its device can be configured as a tube ("compression-fitted sleeve" (Hossainy, col. 3, l. 8) (FF 3))) that exerts sufficient force to avoid collapsing when subjected to compressive forces, a preponderance of the evidence supports the reasonableness of the Examiner's finding that the outer covering of Hossainy's device can be considered a "stent," when that term is given its broadest reasonable interpretation consistent with the Specification.

Appellants argue that Hossainy discloses that the purpose of the bands 209 on the outer surface of the devices is to deliver therapeutic compounds (App. Br. 14). Appellants argue that Hossainy never refers to the regioselective materials as stents, whereas the inner structures 100, 200, and 300 are consistently referred to as stents (*id.*). Moreover, Appellants argue, Hossainy's disclosure demonstrates a recognition that stents are

devices recognized in the art as being useful in specific procedures, such as percutaneous transluminal angioplasty (*id.* at 15).

We are not persuaded by these arguments. It may be true that the purpose of Hossainy's outer covering is to deliver therapeutic agents (*see* FF 4), and that Hossainy does not refer to the device's covering as a stent despite referring to other structures as stents. However, as discussed above, because Hossainy discloses that the outer covering of its device can be configured as a sleeve or tube that exerts sufficient force to avoid collapsing when subjected to compressive forces, we agree with the Examiner that it was reasonable to conclude that Hossainy's outer covering can function as a stent, when that term is given its broadest reasonable interpretation consistent with the Specification. That is, even if the outer covering is used for a different purpose, a preponderance of the evidence shows that the sleeve embodiment of Hossainy's can function as a stent, which is all that the claim requires. *See Swinehart*, 439 F.2d at 213.

In sum, Appellants have not, in our view, adequately rebutted the Examiner's prima facie case of anticipation. Therefore, because a preponderance of the evidence shows that the Examiner reasonably found that the outer covering of Hossainy's device meets the limitation in claim 23 requiring the claimed device to have an outer "biocompatible stent," we affirm the Examiner's rejection of claim 23 as anticipated by Hossainy. Because they were not argued separately, claims 2, 3, 7, 22, 24, 28, 30, 31, and 32 fall with claim 23. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellants argue that method claims 29 and 33-35 are not anticipated by Hossainy, for essentially the same reasons:

> As previously explained, there is only one stent included in the Hossainy *et al.* so-called disclosed composite stent structures. . . . Accordingly, Hossainy *et al.* do not disclose or suggest a method for inserting and expanding any composite stent that includes an inner stent within an outer stent as required by method claims 29 and 33-35.

(App. Br. 16.)

Moreover, Appellants argue, "in not disclosing or suggesting any combination of an inner and outer stent to form a composite stent, Hossainy *et al.* fail to disclose or suggest a method for transporting a substance through such a composite stent structure as is covered in claim 29" (*id.*).

We are not persuaded by these arguments. As discussed above, we do not agree with Appellants that Hossainy fails to disclose a device having both an inner and outer stent. Moreover, Hossainy discloses deploying its composite device by expansion (FF 8) into a vessel to allow the vessel to function normally (*see* FF 2).

We therefore also affirm the Examiner's rejection of claims 29 and 33-35 as being anticipated by Hossainy.

SUMMARY

We affirm the Examiner's rejection of claims 2, 3, 7, 22-24, and 28-35, under 35 U.S.C. § 102(e) as anticipated by Hossainy.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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